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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,946	06/11/2007	Jens Egebjerg Nielsen	P69516US1	2115

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JACOBSON HOLMAN PLLC  
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EXAMINER
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WILSON, LARRY ROSS

ART UNIT	PAPER NUMBER
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3767

MAIL DATE	DELIVERY MODE
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10/27/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/589,946	<b>Applicant(s)</b> NIELSEN ET AL.	
	<b>Examiner</b> LARRY R. WILSON	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 14-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>19 July 2007</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Specification***

1. The abstract of the disclosure is objected to because the specification is not written in idiomatic English and incorporate legal phraseology. Correction is required. See MPEP § 608.01(b).

### ***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 14-18, 21, and 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 4,755,173 to April A. Konopka (Konopka).

In regards to claims 14-18, 21, and 23-24, Konopka discloses an infusion device (Fig. 1, #10) comprising a base element (Fig. 4, #12), fluid receiving means (Fig. 4, #50), fluid communication means (Fig. 12, #14), at least one recess (Fig. 4, # 68), a septum housing (Fig. 7A, #56) accommodating said septum (Fig. 4, #52, 54), septum secured to base by housing (Fig. 4, #56), fluid transfer volume in at least one recess between inner surface of septum and inner section of said recess (Fig. 4, #50), volume communicating with fluid communication means (col. 7, lines 34-39), wherein septum is radially compressed (col. 8, lines 18-20); fluid transfer volume is accommodating cannula securing means (col. 6, lines 20-22); septum housing is a tubular element accommodating septum (Fig. 1, #48), at least one end forming a substantially partial enclosure over one surface of septum (Fig. 4, #68); septum housing includes integrally formed cannula bushing (lower surface of Fig. 7A, #68 and upper surface of support ledge #48 by compression force inherently forms a bushing); one surface of septum substantially

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exposed (Fig. 4, #54), septum housing is fixed to base by welding (col. 9, lines 43-46); septum housing is fixed to said base element by ultrasonic welding (col. 9, lines 43-46); septum housing is fixed to said base element by snap lock (col. 9, lines 43-46); septum housing fluid sealed by ultrasonic welding (col. 9, lines 43-46 – inherent since the cap 56 provides compressive force to the septum that when this is sealed using welding as disclosed the housing would also be fluid sealed); septum housing is fluid-sealed by a gasket between septum housing and inner section of recess (Fig. 7A, #152 – vulcanized silicone forms seal and gasket between hub 48 and cap 56); septum is fixed inside housing by friction (col. 8, lines 32-34 – a component is sized larger than the holder to retain it inherently forms a friction fit).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Konopka.

In regards to claims 25-26, Konopka teaches the infusion device of claim 14 (see above) but does not teach septum is fixed inside septum housing by welding or by ultrasonic welding.

However, Konopka does teach that “septum layers 52, 54 may be sealably bonded to upper portion of the hub 48 so as to cover or seal the chamber 50” (col. 9, lines 30-32)

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and further teaches that “This cap 56 may be secured in place either by ... a sonic seal ...” (col. 9, lines 43-44).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have welded or ultrasonically welded the septum to the septum housing as taught by Konopka for other components in order to provide a seal that maintains sterility of fluid chamber.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LARRY R. WILSON whose telephone number is (571)270-5899. The examiner can normally be reached on Monday-Thursday 7:00 AM - 5:30 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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LRW

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767